

Atty Dkt. No.: LITL-040/LPS-149  
USPN: 09/988,494

### REMARKS

#### Formal Matters

Claims 1-10 and 33-42 are pending after entry of the amendments set forth herein.

Claims 1-10 and 33-42 were examined. Claims 1-10 and 33-42 were rejected.

Claims 33 and 35-41 are amended. The amendments to these claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. New matter has been added by these amendments.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

#### Claim objections

Claims 35-41 are objected to as being substantial duplicates of claims 5-11.

Without wishing to acquiesce to the correctness of this objection, the dependencies of claims 35-41 are amended. Each of these claims depends, directly or indirectly, on claim 34.

The Applicants respectfully submit that this objection has been adequately addressed, and, accordingly this objection may be withdrawn.

#### Rejections under 35 U.S.C. § 112, first paragraph

Claims 33, 34 and claims dependent therefrom are rejected as failing to comply with the written description requirement. Specifically, the Office Action asserts that the new limitations "a molar ratio of about 0.02 to about 17" and "a molar ratio of about 50 to about 800", as entered in response to the previous Office Action, represents new matter. The Applicants respectfully traverse this rejection.

Page 7, lines 4-6, of the instant specification recites: "The ratio of flavin stabilizing component to tetrazolium dye in the composition typically ranges from about 0.02 to about 17" and page 6, lines 28-29, of the instant the specification recites: "The ratio of Group IIIA stabilizing component to tetrazolium dye in the composition typically ranges from about 50 to about 800". Accordingly, the instant specification has clear, literal, support for "a ratio of about 0.02 to about 17" and "a ratio of about 50 to about 800", as recited in the claims. One of skill in the art would recognize that these ratios are

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*molar* ratio because the instant application, on page 5, lines 26-28, recites that "The concentration of the dye reagent in many embodiments ranges from about 1.5 mM to about 50 mM...", and, on page 7, lines 7-8 recites "the concentration of flavin stabilizing reagents in the composition ranges from about 1 mM to about 25 mM...". Accordingly, the specification states that a composition may contain a dye reagent at a concentration of about 1.5-50 mM, and a flavin agent at a concentration of about 1-25mM. An analysis of these molar concentrations indicates that the dye reagent and the flavin stabilizing agent can be present at a *molar* ratio of about 0.02 (i.e., 50 mM dye: 1mM flavin – a ratio of 0.02), or about 17 (i.e., 1.5 mM dye: 25 mM flavin – a ratio of 16.6). Accordingly, the Applicants respectfully submit that the ratios to which the specification refers on pages 6 and 7 are *molar* ratios, rather weight ratios.

In view of the foregoing, the Applicants respectfully submit that there is support for "a molar ratio of about 0.02 to about 17" and "a molar ratio of about 50 to about 800" in the instant specification. Accordingly, this rejection may be withdrawn.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claim 33 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "the method".

Without wishing to acquiesce to the correctness of this rejection, claim 33 is amended to recite "the composition".

The Applicants respectfully submit that this rejection has been adequately addressed, and, accordingly this rejection may be withdrawn.

**Rejections under 35 U.S.C. §102- Ouyang**

Claims 1, 2, 4-10 and 35-42 are rejected under 35 U.S.C. §102(a) as anticipated by Ouyang. The Applicants respectfully traverse this rejection.

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All of the rejected claims recite an "effective amount" of flavin for composition stabilization. The Applicants respectfully argue that the cited references disclose compositions having amounts of flavin that are well below the claim-recited amounts, and, accordingly, the cited references cannot anticipate the claims.

While the Office acknowledges that the cited art does not disclose compositions containing flavin at amounts effective for composition stabilization, the Office Action states that the Applicants' arguments are unpersuasive because the claims do not recite any features that distinguish them from the cited art. According to the Office, such limitations would have to be read into the claims from the specification. The claims are therefore rejected because the phrase "...in an amount effective to stabilize said composition", as recited in the rejected claims, appears to have been given no weight.

However, the Applicants respectfully submit that this phrase "...in an amount effective to stabilize said composition" carries weight, and adequately distinguishes the claimed subject matter from other compositions which contain flavin at much lower amounts. Accordingly, when read correctly, the rejected claims are not anticipated by the cited references and this rejection may be withdrawn.

The MPEP and U.S. Patent and Trademark Office precedent supports the Applicants' position.

With specific reference to claims that recite the phrase "an effective amount", the MPEP 2173.05(c) states that phrase "an effective amount" meets the requirements of 35 U.S.C. § 112, second paragraph, and is a definite and clear claim limitation when the claim states the function which is to be achieved. Accordingly, the phrase "in an amount effective to stabilize said composition", as recited in the rejected claims, meets the requirements of 35 U.S.C. § 112, second paragraph and is a claim limitation just like any other claim limitation. As such, this "effective amount" limitation, as found in the instant claims, limits the claimed compositions to only those containing a flavin agent in an amount that provides for composition stabilization. Since such compositions are not found in the cited art, they cannot anticipate the rejected claims.

In other words, the Applicants respectfully submit that the phrase "...in an amount effective to stabilize said composition", as found in the rejected claims, is either being overlooked or interpreted by the Office to mean "any amount", in order to establish this rejection. Since the phrase "...in an amount effective to stabilize said composition" is definite, according to the MPEP, it carries weight, and,

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accordingly, adequately distinguishes the claimed subject matter from the teachings of the cited art. On the basis of this argument alone, this rejection may be withdrawn.

Further, a search of the U.S. Patent and Trademark Office's online patent database using the search term "effective amount" reveals that over 73,000 patents have been issued with claims that include the limitation "effective amount". Accordingly, the Applicants respectfully submit that "effective amount" is a term that is commonly used to limit patent claims.

For the record, if this rejection is to be maintained, the Applicants respectfully request that the Office sets forth the reasoning why the phrase "...in an amount effective..", as used in the instant claims carries no weight while "effective amount", as found in the claims of over 73,000 issued patents, does.

Accordingly, in view of the foregoing discussion, the Applicants respectfully submit that the rejected claims require that the claimed compositions have an effective amount of flavin for stabilization of the composition. The cited art discloses compositions containing flavin as an enzyme cofactor and accordingly disclose compositions that contain flavin at much lower amounts than those instantly claimed. It follows from the foregoing that the claimed subject matter is distinguishable from the compositions described in the cited art because the claimed subject matter contains an amount of flavin agent effective for stabilization, and the cited art compositions do not. Since this requirement is recited in the claims, the cited art cannot anticipate the claimed invention.

The Applicants respectfully submit that the foregoing discussion adequately addresses the rejections of the claims under 35 U.S.C. § 102. In view of the foregoing, withdrawal of these rejections is respectfully requested.

**Rejections under 35 U.S.C. §102- Nippon Chemiphar**

Claims 1, 2, 4, 5, 8, 9, 35, 36, 39 and 40 are rejected under 35 U.S.C. §102(b) as anticipated by Nippon Chemiphar. The Applicants respectfully traverse this rejection.

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All of the rejected claims recite an "effective amount" of flavin for composition stabilization. As argued above, the Applicants respectfully argue that the cited references disclose compositions having amounts of flavin that are well below the claim-recited amounts, and, accordingly, the cited references cannot anticipate the claims.

While the Office acknowledges that the cited art does not disclose compositions containing flavin at amounts effective for composition stabilization, the Office Action states that the Applicants' arguments are unpersuasive because the claims do not recite any features that distinguish them from the cited art. According to the Office, such limitations would have to be read into the claims from the specification. The claims are therefore rejected because the phrase "...in an amount effective to stabilize said composition", as recited in the rejected claims, appears to have been given no weight.

However, the Applicants respectfully submit that this phrase "...in an amount effective to stabilize said composition" carries weight, and adequately distinguishes the claimed subject matter from other compositions which contain flavin at much lower amounts. Accordingly, when read correctly, the rejected claims are not anticipated by the cited references and this rejection may be withdrawn.

Again, the MPEP and U.S. Patent and Trademark Office precedent supports the Applicants' position.

With specific reference to claims that recite the phrase "an effective amount", the MPEP 2173.05(c) states that phrase "an effective amount" meets the requirements of 35 U.S.C. § 112, second paragraph, and is a definite and clear claim limitation when the claim states the function that is to be achieved. Accordingly, the phrase "in an amount effective to stabilize said composition", as recited in the rejected claims, meets the requirements of 35 U.S.C. § 112, second paragraph and is a claim limitation just like any other claim limitation. As such, this "effective amount" limitation, as found in the instant claims, limits the claimed compositions to only those containing a flavin agent in an amount that provides for composition stabilization. Since such compositions are not found in the cited art, they cannot anticipate the rejected claims.

In other words, the Applicants respectfully submit that the phrase "...in an amount effective to stabilize said composition", as found in the rejected claims, is either being overlooked or interpreted by the Office to mean "any amount", in order to establish this rejection. Since the phrase "...in an amount effective to stabilize said composition" is definite, according to the MPEP, it carries weight, and,

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accordingly, adequately distinguishes the claimed subject matter from the teachings of the cited art. On the basis of this argument alone, this rejection may be withdrawn.

Further, a search of the U.S. Patent and Trademark Office's online patent database using the search term "effective amount" reveals that over 73,000 patents have been issued with claims that include the limitation "effective amount". Accordingly, the Applicants respectfully submit that "effective amount" is a term that is commonly used to limit patent claims.

For the record, if this rejection is to be maintained, the Applicants respectfully request that the Office sets forth the reasoning why the phrase "...in an amount effective..", as used in the instant claims carries no weight while "effective amount", as found in the claims of over 73,000 issued patents, does.

Accordingly, in view of the foregoing discussion, the Applicants respectfully submit that the rejected claims require that the claimed compositions have an effective amount of flavin for stabilization of the composition. The cited art discloses compositions containing flavin as an enzyme cofactor and accordingly disclose compositions that contain flavin at much lower amounts than those instantly claimed. It follows from the foregoing that the claimed subject matter is distinguishable from the compositions described in the cited art because the claimed subject matter contains an amount of flavin agent effective for stabilization, and the cited art compositions do not. Since this requirement is recited in the claims, the cited art cannot anticipate the claimed invention.

The Applicants respectfully submit that the foregoing discussion adequately addresses the rejections of the claims under 35 U.S.C. § 102. In view of the foregoing, withdrawal of these rejections is respectfully requested.

#### **Rejections under 35 U.S.C. §102- Steinbach**

Claims 1, 2, 4, 6, 8, 35, 37, 39 are rejected under 35 U.S.C. §102(b) as anticipated by Steinbach. The Applicants respectfully traverse this rejection.

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All of the rejected claims recite an "effective amount" of flavin for composition stabilization. As argued above, the Applicants respectfully argue that the cited references disclose compositions having amounts of flavin that are well below the claim-recited amounts, and, accordingly, the cited references cannot anticipate the claims.

While the Office acknowledges that the cited art does not disclose compositions containing flavin at amounts effective for composition stabilization, the Office Action states that the Applicants' arguments are unpersuasive because the claims do not recite any features that distinguish them from the cited art. According to the Office, such limitations would have to be read into the claims from the specification. The claims are therefore rejected because the phrase "...in an amount effective to stabilize said composition", as recited in the rejected claims, appears to have been given no weight.

However, the Applicants respectfully submit that this phrase "...in an amount effective to stabilize said composition" carries weight, and adequately distinguishes the claimed subject matter from other compositions which contain flavin at much lower amounts. Accordingly, when read correctly, the rejected claims are not anticipated by the cited references and this rejection may be withdrawn.

The MPEP and U.S. Patent and Trademark Office precedent supports the Applicants' position.

With specific reference to claims that recite the phrase "an effective amount", the MPEP 2173.05(c) states that phrase "an effective amount" meets the requirements of 35 U.S.C. § 112, second paragraph, and is a definite and clear claim limitation when the claim states the function which is to be achieved. Accordingly, the phrase "in an amount effective to stabilize said composition", as recited in the rejected claims, meets the requirements of 35 U.S.C. § 112, second paragraph and is a claim limitation just like any other claim limitation. As such, this "effective amount" limitation, as found in the instant claims, limits the claimed compositions to only those containing a flavin agent in an amount that provides for composition stabilization. Since such compositions are not found in the cited art, they cannot anticipate the rejected claims.

In other words, the Applicants respectfully submit that the phrase "...in an amount effective to stabilize said composition", as found in the rejected claims, is either being overlooked or interpreted by the Office to mean "any amount", in order to establish this rejection. Since the phrase "...in an amount effective to stabilize said composition" is definite, according to the MPEP, it carries weight, and,

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accordingly, adequately distinguishes the claimed subject matter from the teachings of the cited art. On the basis of this argument alone, this rejection may be withdrawn.

Further, a search of the U.S. Patent and Trademark Office's online patent database using the search term "effective amount" reveals that over 73,000 patents have been issued with claims that include the limitation "effective amount". Accordingly, the Applicants respectfully submit that "effective amount" is a term that is commonly used to limit patent claims.

For the record, if this rejection is to be maintained, the Applicants respectfully request that the Office sets forth the reasoning why the phrase "...in an amount effective..", as used in the instant claims carries no weight while "effective amount", as found in the claims of over 73,000 issued patents, does.

Accordingly, in view of the foregoing discussion, the Applicants respectfully submit that the rejected claims require that the claimed compositions have an effective amount of flavin for stabilization of the composition. The cited art discloses compositions containing flavin as an enzyme cofactor and accordingly disclose compositions that contain flavin at much lower amounts than those instantly claimed. It follows from the foregoing that the claimed subject matter is distinguishable from the compositions described in the cited art because the claimed subject matter contains an amount of flavin agent effective for stabilization, and the cited art compositions don't. Since this requirement is recited in the claims, the cited art cannot anticipate the claimed invention.

The Applicants respectfully submit that the foregoing discussion adequately addresses the rejections of the claims under 35 U.S.C. § 102. In view of the foregoing, withdrawal of these rejections is respectfully requested.

**Rejection under 35 U.S.C. §103 – Nippon and Geisler**

Claims 1-10 and 33-42 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Nippon and Geisler. The Applicants respectfully traverse this rejection.

The rejected claims are directed to compositions containing: a flavin agent present in an amount effective to stabilize the composition (claims 1-10 and 33), a Group IIIA compound present at a molar ratio of about 50-800 (claims 34-41), or both a flavin agent and a Group IIIA compound (claim 42).



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The Applicants respectfully submit that both Nippon and Geisler fail to disclose, teach or fairly suggest any of these features. Accordingly, the cited references, taken separately or in any combination, fail to teach at least one element of each of the rejected claims. For this reason alone, the above rejection may be withdrawn.

Further, the Applicants respectfully submit that the compositions possess an unexpected property, i.e., stability, that is not fairly taught or suggested in the cited art. According to current law and the guidance set forth in the MPEP, the claimed compositions cannot be obvious in view of the cited art and, accordingly, this rejection may be withdrawn.

As discussed in great detail in MPEP § 716.02(a), a rejection that is based on obviousness may be rebutted if the claimed invention shows an unexpected or superior property, in relation to any cited art. For example, MPEP § 716.02(a) recites "Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness".

Accordingly, if the claimed compositions possess an unexpected property that is not suggested by the cited art, the claimed compositions must be unobvious in view of the cited art.

The Applicants respectfully submit that the claimed compositions have an unexpected property: stability. These unexpected properties are best seen in Figs 1-3 of the instant application, where results show that the claimed compositions are unexpectedly stable at 56°C for one week. Figures 1, 2 and 3 respectively show that the presence of a borax, FAD, and borax and FAD dramatically increase the stability of a signal producing system over a signal producing system in the absence of FAD.

In no way is this unexpected property of the claimed composition suggested by the cited art. Accordingly, even if the cited art could be construed as suggesting all of the elements of the claimed invention, according to the MPEP, the cited art still cannot render the claimed subject matter obvious.

Finally, the Office has attempted to establish these rejections by arguing that "at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation" and "one of skill in the art would have been motivated by routine practice to optimize the reagents of ..... with a reasonable expectation for successfully obtaining an effective reagent composition."

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However, the Office has not stated what would motivate one of skill in the art to add such large amounts of flavin/group III compounds to the prior art compositions and then test those compositions for increased stability. Without such motivation, the Applicants respectfully ask why one of skill in the art would produce the claimed invention by routine experimentation? If this rejection is to be maintained, for the record, the Applicants respectfully request that the Examiner address this point specifically.

The Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §103 has been adequately addressed. Withdrawal of this rejection is respectfully requested.

**Rejection under 35 U.S.C. §103 – Ouyang**

Claims 1-2, 4-10, 33 and 35-41 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Ouyang. The Applicants respectfully traverse this rejection.

The rejected claims are directed to compositions containing a flavin agent present in an amount effective to stabilize the composition.

The Applicants respectfully submit that Ouyang fails to disclose, teach or fairly suggest this feature. Accordingly, Ouyang fails to teach at least one element of each of the claims. For this reason alone, the above rejection may be withdrawn.

Further, the Applicants respectfully submit that the compositions possess an unexpected property, i.e., stability, that is not fairly taught or suggested in the cited art. According to current law and the guidance set forth in the MPEP, the claimed compositions cannot be obvious in view of the cited art and, accordingly, this rejection may be withdrawn.

As discussed in great detail in MPEP § 716.02(a), a rejection that is based on obviousness may be rebutted if the claimed invention shows an unexpected or superior property, in relation to any cited art. For example, MPEP § 716.02(a) recites "Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness".

Accordingly, if the claimed compositions possess an unexpected property that is not suggested by the cited art, the claimed compositions must be unobvious in view of the cited art.

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The Applicants respectfully submit that the claimed compositions have an unexpected property: stability. These unexpected properties are best seen in Fig. 2 of the instant application, where results show that the claimed compositions are unexpectedly stable at 56°C for one week. Figure 2 shows that the presence of FAD dramatically increase the stability of a signal producing system over a signal producing system in the absence of these compounds.

In no way is this unexpected property of the claimed composition suggested by the cited art. Accordingly, even if the cited art could be construed as suggesting all of the elements of the claimed invention, according to the MPEP, the cited art still cannot render the claimed subject matter obvious.

Finally, the Office has attempted to establish these rejections by arguing that "at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation" and "one of skill in the art would have been motivated by routine practice to optimize the reagents of ..... with a reasonable expectation for successfully obtaining an effective reagent composition."

However, the Office has not stated what would motivate one of skill in the art to add such large amounts of a flavin compound to the prior art compositions and then test those compositions for increased stability. Without such motivation, the Applicants respectfully ask why one of skill in the art would produce the claimed invention by routine experimentation? If this rejection is to be maintained, for the record, the Applicants respectfully request that the Examiner address this point specifically.

The Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §103 has been adequately addressed. Withdrawal of this rejection is respectfully requested.

#### **Rejection under 35 U.S.C. §103 – Nippon**

Claims 1-2, 4-5, 8-9, 33, 35-36 and 39-40 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Nippon. The Applicants respectfully traverse this rejection.

The rejected claims are directed to compositions containing a flavin agent present in an amount effective to stabilize the composition.

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The Applicants respectfully submit that Nippon fails to disclose, teach or fairly suggest this feature. Accordingly Nippon fails to teach at least one element of each of the claims. For this reason alone, the above rejection may be withdrawn.

Further, the Applicants respectfully submit that the compositions possess an unexpected property, i.e., stability, that is not fairly taught or suggested in the cited art. According to current law and the guidance set forth in the MPEP, the claimed compositions cannot be obvious in view of the cited art and, accordingly, this rejection may be withdrawn.

As discussed in great detail in MPEP § 716.02(a), a rejection that is based on obviousness may be rebutted if the claimed invention shows an unexpected or superior property, in relation to any cited art. For example, MPEP § 716.02(a) recites "Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness".

Accordingly, if the claimed compositions possess an unexpected property that is not suggested by the cited art, the claimed compositions must be unobvious in view of the cited art.

The Applicants respectfully submit that the claimed compositions have an unexpected property: stability. These unexpected properties are best seen in Fig. 2 of the instant application, where results show that the claimed compositions are unexpectedly stable at 56°C for one week. Figure 2 shows that the presence of FAD dramatically increase the stability of a signal producing system over a signal producing system in the absence of these compounds.

In no way is this unexpected property of the claimed composition suggested by the cited art. Accordingly, even if the cited art could be construed as suggesting all of the elements of the claimed invention, according to the MPEP, the cited art still cannot render the claimed subject matter obvious.

Finally, the Office has attempted to establish these rejections by arguing that "at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation" and "one of skill in the art would have been motivated by routine practice to optimize the reagents of ..... with a reasonable expectation for successfully obtaining an effective reagent composition."

However, the Office has not stated what would motivate one of skill in the art to add such large amounts of a flavin compound to the prior art compositions and then test those compositions for

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increased stability. Without such motivation, the Applicants respectfully ask why one of skill in the art would produce the claimed invention by routine experimentation? If this rejection is to be maintained, for the record, the Applicants respectfully request that the Examiner address this point specifically.

The Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §103 has been adequately addressed. Withdrawal of this rejection is respectfully requested.

#### **Rejection under 35 U.S.C. §103 – Steinbach**

Claims 1, 2, 4, 6, 8, 33, 37 and 39 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Steinbach. The Applicants respectfully traverse this rejection.

The rejected claims are directed to compositions containing a flavin agent present in an amount effective to stabilize the composition.

The Applicants respectfully submit that Steinbach fails to disclose, teach or fairly suggest this feature. Accordingly Steinbach fails to teach at least one element of each of the claims. For this reason alone, the above rejection may be withdrawn.

Further, the Applicants respectfully submit that the compositions possess an unexpected property, i.e., stability, that is not fairly taught or suggested in the cited art. According to current law and the guidance set forth in the MPEP, the claimed compositions cannot be obvious in view of the cited art and, accordingly, this rejection may be withdrawn.

As discussed in great detail in MPEP § 716.02(a), a rejection that is based on obviousness may be rebutted if the claimed invention shows an unexpected or superior property, in relation to any cited art. For example, MPEP § 716.02(a) recites "Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness".

Accordingly, if the claimed compositions possess an unexpected property that is not suggested by the cited art, the claimed compositions must be unobvious in view of the cited art.

The Applicants respectfully submit that the claimed compositions have an unexpected property: stability. These unexpected properties are best seen in Fig. 2 of the instant application, where results show that the claimed compositions are unexpectedly stable at 56°C for one week. Figure 2 shows that

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the presence of FAD dramatically increase the stability of a signal producing system over a signal producing system in the absence of these compounds.

In no way is this unexpected property of the claimed composition suggested by the cited art. Accordingly, even if the cited art could be construed as suggesting all of the elements of the claimed invention, according to the MPEP, the cited art still cannot render the claimed subject matter obvious.

Finally, the Office has attempted to establish these rejections by arguing that "at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation" and "one of skill in the art would have been motivated by routine practice to optimize the reagents of ..... with a reasonable expectation for successfully obtaining an effective reagent composition."

However, the Office has not stated what would motivate one of skill in the art to add such large amounts of a flavin compound to the prior art compositions and then test those compositions for increased stability. Without such motivation, the Applicants respectfully ask why one of skill in the art would produce the claimed invention by routine experimentation? If this rejection is to be maintained, for the record, the Applicants respectfully request that the Examiner address this point specifically.

The Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §103 has been adequately addressed. Withdrawal of this rejection is respectfully requested.

#### **Rejection under 35 U.S.C. §103 – Geisler**

Claims 34, 35, 37, and 39-41 are rejected under 35 U.S.C. §103(a) as unpatentable in view of Geisler. The Applicants respectfully traverse this rejection.

The rejected claims are directed to compositions containing a Group III agent present at a molar ratio of about 50 to about 800.

The Applicants respectfully submit that Geisler fails to disclose, teach or fairly suggest this feature. Accordingly Geisler fails to teach at least one element of each of the claims. For this reason alone, the above rejection may be withdrawn.

Further, the Applicants respectfully submit that the compositions possess an unexpected property, i.e., stability, that is not fairly taught or suggested in the cited art. According to current law and

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the guidance set forth in the MPEP, the claimed compositions cannot be obvious in view of the cited art and, accordingly, this rejection may be withdrawn.

As discussed in great detail in MPEP § 716.02(a), a rejection that is based on obviousness may be rebutted if the claimed invention shows an unexpected or superior property, in relation to any cited art. For example, MPEP § 716.02(a) recites "Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness".

Accordingly, if the claimed compositions possess an unexpected property that is not suggested by the cited art, the claimed compositions must be unobvious in view of the cited art.

The Applicants respectfully submit that the claimed compositions have an unexpected property: stability. These unexpected properties are best seen in Fig. 1 of the instant application, where results show that the claimed compositions are unexpectedly stable at 56°C for one week. Figure 1 shows that the presence of borax dramatically increase the stability of a signal producing system over a signal producing system in the absence of these compounds.

In no way is this unexpected property of the claimed composition suggested by the cited art. Accordingly, even if the cited art could be construed as suggesting all of the elements of the claimed invention, according to the MPEP, the cited art still cannot render the claimed subject matter obvious.

Finally, the Office has attempted to establish these rejections by arguing that "at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation" and "one of skill in the art would have been motivated by routine practice to optimize the reagents of ..... with a reasonable expectation for successfully obtaining an effective reagent composition."

However, the Office has not stated what would motivate one of skill in the art to add such large amounts of a Group III compound to the prior art compositions and then test those compositions for increased stability. Without such motivation, the Applicants respectfully ask why one of skill in the art would produce the claimed invention by routine experimentation? If this rejection is to be maintained, for the record, the Applicants respectfully request that the Examiner address this point specifically.

The Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §103 has been adequately addressed. Withdrawal of this rejection is respectfully requested.

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**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-040.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 1.20.04

By: 

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